DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express
Our ref: 29-16596

Warning Letter

March 10, 2000

D. Keith Grossman
President and CEO
Thoratec Laboratories Corporation
6035 Stoneridge Dr.
Pleasanton, CA 94588

Dear Mr. Grossman:

An inspection was conducted of your firm, Thoratec Laboratories Corporation, between January 18 and 24, 2000 by Engineer Norman Wong and Investigator Mark Chan. The inspection found that your firm manufactures the Thoratec Ventricular Assist Device (VAD) System. This product is a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

The inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with the Quality Systems Regulation (QSR) for medical devices as set forth in Title 21, Code of Federal Regulations (CFR) Part 820 as follows:

1. Your firm's Quality Manual is not complete in that it only specifies the frequency of the management reviews, not what material and topics are to be reviewed. Additionally, there is no reference that an agenda for the review sessions will provide further details of the topics to be discussed. Without such specificity, we are unable to determine whether your reviews satisfy the requirements of the Quality System Regulation. [21 CFR 820.20(c)]

2. Your employee training practices are inadequate in several respects. For instance, during the inspection, your firm was unable to produce written confirmation that employees had been trained in such duties as soldering, connector crimping, and connector assembly. You have received at least four complaints which involve dislodging of connectors or of crimp failures. [21 CFR 820.25(b)]

3. Your acceptance procedures for incoming components, in-process devices, and finished devices are deficient in several respects. As an example, there is no dimensional verification for the female/male connector constituent to assure proper fit. Additionally, there does not appear to be any acceptance activity performed on

the suitability of wires, crimps, and connectors on the uninterruptable power supply (UPS). The inspection also found that there are neither minimum specifications nor quantitative tests for the parting strength of crimps and connector assemblies. [21 CFR 820.80]

4. The implementation of corrective and preventative action (CAPA) procedures at your firm is incomplete in that your procedures do not include reference to the Access electronic database. This database captures information from sources such as complaints and nonconformance reports for use during management reviews. In addition, battery assembly defects, such as loose connectors, were recognized by the UPS assembly inspector. However, the defective assemblies were reworked without generation of a nonconforming product report. [21CFR 820.100(b)]

The FDA inspection also revealed that your device is misbranded within the meaning of Section 502(t)(2) of the Act. Your firm failed to submit information to FDA as required by the Medical Device Reporting Regulation, 21 CFR Part 803.

Specifically, your firm failed to notify FDA of malfunctions that may cause or contribute to serious injuries. Two complaints, #547 and #443, both involved compressor shutdown of the drive console during use by the patient. These events are reportable malfunctions, because the device or a similar device would be likely to cause or contribute to a death or serious injury if the malfunction was to recur.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA483 issued to you may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined by be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, requests for Certificates of Exportability and to Foreign Governments will not be cleared until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action

cannot be completed within 15 working days, state the reason for the delay and the date on which the correction will be completed.

Your response should be sent to the following individual:

Andrea P. Scott
Supervisory Investigator/Compliance Officer
U. S. Food & Drug Administration
96 North Third St., Suite 325
San Jose, CA 95112

Sincerely,

Charles D. Moss

Charles D. Moss
Acting Director
San Francisco District